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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,121	11/13/2001	Kevin R. McIntosh	640100-441	5983

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EXAMINER

BELYAVSKYI, MICHAEL A

ART UNIT	PAPER NUMBER
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1644

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DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/067,121

Applicant(s)

MCINTOSH ET AL.

Examiner

Michail A Belyavskyi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47-95 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 47-95 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. Applicant's amendment, filed 11/13/01 (Paper No. 2), is acknowledged.
2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 93-134 have been renumbered as claims 47-95 respectively.

Claims 47-95 are pending.

Restriction Requirement

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
 - I. Claims 47-49, 51- 65,67 and 70 drawn to a process for reducing an immune response of the effector cells against an alloantigen, wherein T cells from donor, alloantigen from recipient and mesenchymal stem cells are xenogenic to the donor of the transplant, classified in Class 435, subclasses 325, 375 and 383; class 424 subclasses 93.7, 577.
 - II. Claims 47-49, 51- 65, 68 and 70 drawn to a process for reducing an immune response of the effector cells against an alloantigen, wherein T cells from donor, alloantigen from recipient and mesenchymal stem cells are xenogenic to the recipient of the transplant, classified in Class 435, subclasses 325, 375 and 383; class 424 subclasses 93.7, 577.
 - III. Claims 47-49, 51- 65, 69 and 70 drawn to a process for reducing an immune response of the effector cells against an alloantigen, wherein T cells from donor, alloantigen from recipient and mesenchymal stem cells are xenogenic to both the donor and the recipient of the transplant, classified in Class 435, subclasses 325, 375 and 383; class 424 subclasses 93.7, 577.
 - IV. Claims 47-48, 50 - 67 and 70 drawn to a process for reducing an immune response of the effector cells against an alloantigen, wherein T cells from recipient, alloantigen from donor and mesenchymal stem cells are xenogenic to the donor of the transplant, classified in Class 435, subclasses 325, 375 and 383; class 424 subclasses 93.7, 577.

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- V. Claims 47-48, 50 – 66, 68 and 70 drawn to a process for reducing an immune response of the effector cells against an alloantigen, wherein T cells from recipient, alloantigen from donor and mesenchymal stem cells are xenogenic to the recipient of the transplant, classified in Class 435, subclasses 325, 375 and 383; class 424 subclasses 93.7, 577.
- VI. Claims 47-48, 50 – 66, 69 and 70 drawn to a process for reducing an immune response of the effector cells against an alloantigen, wherein T cells from recipient, alloantigen from donor and mesenchymal stem cells are xenogenic to both the donor and the recipient of the transplant, classified in Class 435, subclasses 325, 375 and 383; class 424 subclasses 93.7, 577.
- VII. Claim 71, drawn to a process for treating a transplant recipient for graft versus host disease, comprising treating the recipient of a donor transplant with mesenchymal stem cells, classified in Class 435, subclasses 325, 375 and 383; class 424 subclasses 93.7, 577.
- VIII. Claim 72, drawn to a process for reducing an immune response against an alloantigen, classified in Class 435, subclasses 325, 375 and 383; class 424 subclass 93.7, 577.
- IX. Claims 73, 74, 77, 79 – 81, 85 and 86, drawn to a composition for reducing an adverse immune response against donor transplant and a composition for reducing an adverse immune response against a graft recipient, wherein mesenchymal stem cells are autologous to the recipient, classified in Class 435, subclasses 325, 375, 383 520; class 424 subclass 93.7, 577.
- X. Claims 73, 75, 77, 79, 80, 82, 85 and 86, drawn to a composition for reducing an adverse immune response against donor transplant and a composition for reducing an adverse immune response against a graft recipient, wherein mesenchymal stem cells are autologous to the donor, classified in Class 435, subclasses 325, 375, 383 520; class 424 subclass 93.7, 577.
- XI. Claims 73, 76, 77, 79, 80, 83, 85 and 86, drawn to a composition for reducing an adverse immune response against donor transplant and a composition for reducing an adverse immune response against a graft recipient, wherein mesenchymal stem cells are autologous to both the recipient and the donor, classified in Class 435, subclasses 325, 375, 383 520; class 424 subclass 93.7, 577.

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- XII. Claims 73, 77 - 79, 80, 84- 86, drawn to a composition for reducing an adverse immune response against donor transplant and a composition for reducing an adverse immune response against a graft recipient, wherein mesenchymal stem cells are xenogeneic to both the recipient and the donor, classified in Class 435, subclasses 325, 375, 383 520; class 424 subclass 93.7, 577.
- XIII. Claims 87-89, 91-95 drawn to a process for reducing in a transplant recipient an immune response, wherein T cells from donor and alloantigen from recipient, classified in Class 435, subclasses 325, 375, 383 class 424 subclass 93.7, 577.
- XIV. Claims 87-88, 90-95 drawn to a process for reducing in a transplant recipient an immune response, wherein T cells from recipient and alloantigen from donor, classified in Class 435, subclasses 325, 375, 383; class 424 subclass 93.7, 577.

3. Groups I – VIII and XIII-XIV are different methods. These inventions are different with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

4. Groups IX - XII are different products. These compositions are different with respect to the structure of the molecules within the composition, therefore each product is patentably distinct.

5. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.


6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskiy, Ph.D.
Patent Examiner
Technology Center 1600
February 24, 2003


CHRISTINA CHAN
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